IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY

Master File No. 2:12-MD-02327 MDL 2327

LITIGATION

ETHICON NON-REVISION PTO 298 (ELECTION WAVE) CASES LISTED IN EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

NOTICE OF ADOPTION OF PRIOR DAUBERT MOTION OF TIMOTHY ULATOWSKI, M.D. FOR NON-REVISION PTO 298 (ELECTION WAVE)—WITH ADDITIONAL ARGUMENT

COME NOW, the Plaintiffs, and hereby adopt and incorporate by reference the *Daubert* motion filed against Timothy Ulatowski for Ethicon Wave 1, Dkt. 2060 (motion), 2065 (memorandum in support). Plaintiffs respectfully request that the Court exclude Timothy Ulatowski's testimony for the reasons expressed in the Wave 1 briefing. This notice applies to the Non-Revision PTO 298 (Election Wave) cases identified in Exhibit A attached hereto.

Plaintiffs also note that while Mr. Ulatowski has issued a new report on the Mersilene product, the same arguments that Plaintiffs raised against Mr. Ulatowski in prior briefing apply to his new Mersilene report. In the Wave 1 motion being adopted, the Plaintiffs argued that Mr. Ulatowski should not be permitted to testify because his opinions all bore on FDA issues. This Court has consistently excluded all FDA evidence from mesh trials. *See Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6680356, at *10 (S.D.W. Va. Nov. 25, 2014) (stating that "this court will not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process"). Plaintiffs further argued in Wave 1 that Mr. Ulatowski does not have the expertise to opine about the sufficiency of manufacturing processes or the content of warnings or patient brochures.

Mr. Ulatowski's Mersilene report offers the following opinions, summarized:

- 1) The FDA's clearance of Mersilene established that the product is reasonably safe;
- 2) The material used in Mersilene is safe and effective, as shown by FDA approval of Mersilene sutures;
- 3) FDA rules allow physicians to use any legally marketed device for any condition, regardless of whether the condition appears in the label;
- 4) Clinical literature shows many years of clinical use of Mersilene sutures and mesh; and
- 5) The Mersilene labeling met FDA requirements.

(Ulatowski Mersilene Report, attached as Exhibit B).

These opinions all either bear improperly on FDA issues or are beyond Mr. Ulatowski's expertise, as discussed in the prior brief. So, all of these opinions should be excluded. Four of the five are clearly FDA opinions. Opinion No. 4, regarding literature, is either beyond Mr. Ulatowski's expertise or irrelevant. The fact that he has read certain articles that have discussed Mersilene over time is irrelevant, unless it leads to some conclusion about the safety and efficacy of the product. And Mr. Ulatowski, who is not a physician, does not have the expertise required to opine as to the safety and efficacy of the product.

For these reasons, and those discussed in the Wave 1 motion being adopted, all of Mr. Ulatowski's Mersilene opinions should be excluded. The Court should exclude Mr. Ulatowski's opinions regarding the products on which he previously offered reports for the reasons previously discussed in the Wave 1 motion.

Dated: December 18, 2018 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2018, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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